IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED,	)	
Plaintiffs,	)	C.A. No. 21- 1138-MN
v.	)	
AVADEL PHARMACEUTICALS PLC, AVADEL US HOLDINGS, INC., AVADEL SPECIALTY PHARMACEUTICALS, LLC, AVADEL LEGACY PHARMACEUTICALS, LLC, AVADEL MANAGEMENT CORPORATION and AVADEL CNS PHARMACEUTICALS, LLC,	)	
Defendants.	)	

ANSWER TO COMPLAINT FOR PATENT INFRINGEMENT, DEFENSES AND COUNTERCLAIMS

Preliminary Statement

This case is nothing more than Plaintiff Jazz Pharmaceuticals, Inc.'s ("Jazz") continued assault on Defendant Avadel CNS Pharmaceuticals, LLC's ("Avadel") revolutionary ***once-nightly*** formulation of sodium oxybate, FT218. As stated in Avadel's Answer to Jazz's previously-filed Complaint (C.A. No. 21-691-MN), after years of failed efforts, Jazz does not have its own once-nightly sodium oxybate formulation. Jazz therefore has resorted to filing lawsuits aimed at blocking FT218, including the instant lawsuit in which Jazz asserts a patent directed to "a method of . . . administering a ***single*** daily dose . . . of sodium oxybate." But as described below, Jazz did not invent—and has not invented to this day—a product that can be used in such a method. And the specification of Jazz's patent does not describe such a product and/or method. Rather, Jazz once again copied Avadel. In this case, Jazz prevented its pending patent claims from becoming public, all the while amending those claims to attempt to mirror Avadel's patent claims covering FT218 and never informing the Patent Office of this copying. Such tactics are impermissible, and

render Jazz's patent unenforceable. And in any event, there is no support or disclosure in Jazz's patent specification to support these claims, making Jazz's copycat patent invalid.

Avadel Pharmaceuticals plc, Avadel US Holdings, Inc., Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, Avadel Management Corporation, and Avadel CNS Pharmaceuticals, LLC (collectively, "Defendants") deny that they infringe, have infringed, or will infringe any valid claim of the asserted patent, deny that there is any legitimate basis for the lawsuit brought by Jazz, deny that Jazz is entitled to any relief, and deny the allegations and characterizations in Jazz's Complaint unless expressly admitted as follows:

Nature of the Action

1. This is an action for patent infringement and for a declaratory judgement of patent infringement under the patent laws of the United States, 35 U.S.C. §100, et seq. and 28 U.S.C. §§ 2201 and 2202, arising from Avadel's filing of a New Drug Application ("NDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a sodium oxybate drug product prior to the expiration of United States Patent Nos. 11,077,079 (the "'079 patent" or "the patent-in-suit").

ANSWER: Defendants admit that the Complaint purports to allege an action for patent infringement and for a declaratory judgment of patent infringement under the patent laws of the United States, 35 U.S.C. §100, et seq. and 28 U.S.C. §§ 2201 and 2202, involving United States Patent No. 11,077,079 (the "'079 patent" or "the patent-in-suit"), which states on its face that it is assigned to Jazz Pharmaceuticals Ireland Limited. Defendants admit that Avadel filed an NDA with the FDA seeking approval to commercially market FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. Defendants admit that the patent-in-suit has not yet expired. Defendants deny that the Complaint properly states a claim for patent infringement. Except as otherwise admitted, the allegations are denied as stated.

The Parties

2. Plaintiff Jazz Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 3170 Porter Drive, Palo Alto, California 94304.

ANSWER: Defendants lack sufficient information to form a belief as to the truth of the allegations in Paragraph 2, and therefore deny them.

3. Plaintiff Jazz Pharmaceuticals Ireland Limited is a corporation organized and existing under the laws of Ireland, having a principal place of business at Waterloo Exchange, Waterloo Road, Dublin, Ireland 4.

ANSWER: Defendants lack sufficient information to form a belief as to the truth of the allegations in Paragraph 3, and therefore deny them.

4. On information and belief, Defendant Avadel Pharmaceuticals plc is a corporation organized and existing under the laws of Ireland, having a principal place of business at 10 Earlsfort Terrace, Dublin 2, Ireland, D02 T380. On information and belief, Avadel Pharmaceuticals plc is in the business of, *inter alia*, developing, manufacturing, marketing, offering for sale, and selling pharmaceutical products throughout the United States, including within this District, either on its own or through its affiliates, including Avadel US Holdings, Inc., Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, Avadel Management Corporation, and Avadel CNS Pharmaceuticals LLC.

ANSWER: Defendants admit that Avadel Pharmaceuticals plc is a corporation organized and existing under the laws of Ireland and has its principal place of business at 10 Earlsfort Terrace, Dublin 2, Ireland, D02 T380. Except as otherwise admitted, the allegations are denied as stated.

5. On information and belief, Defendant Avadel US Holdings, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri 63005. On information and belief, Avadel US Holdings, Inc. is in the business of, *inter alia*, developing, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products throughout the United States, including within this District, either on its own or through its affiliates, including Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, Avadel Management Corporation, and Avadel CNS Pharmaceuticals LLC.

ANSWER: Defendants admit that Avadel US Holdings, Inc. is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 16640

Chesterfield Grove Road, Suite 200, Chesterfield, Missouri 63005. Except as otherwise admitted, the allegations are denied as stated.

6. On information and belief, Avadel US Holdings, Inc. is a wholly-owned subsidiary of Avadel Pharmaceuticals plc.

ANSWER: Admitted.

7. On information and belief, Defendant Avadel Specialty Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri 63005. On information and belief, Avadel Specialty Pharmaceuticals, LLC is in the business of, *inter alia*, developing, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products throughout the United States, including within this District, either on its own or through its affiliates, including Avadel US Holdings, Inc., Avadel Legacy Pharmaceuticals, LLC, Avadel Management Corporation, and Avadel CNS Pharmaceuticals LLC.

ANSWER: Defendants admit that Avadel Specialty Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware. Except as otherwise admitted, the allegations are denied as stated.

8. On information and belief, Defendant Avadel Legacy Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri 63005. On information and belief, Avadel Legacy Pharmaceuticals, LLC is in the business of, *inter alia*, developing, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products throughout the United States, including within this District, either on its own or through its affiliates, including Avadel US Holdings, Inc., Avadel Specialty Pharmaceuticals, LLC, Avadel Management Corporation, and Avadel CNS Pharmaceuticals LLC.

ANSWER: Defendants admit that Avadel Legacy Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware and has its principal place of business at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri 63005. Except as otherwise admitted, the allegations are denied as stated.

9. On information and belief, Defendant Avadel Management Corporation is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri 63005. On information and belief, Avadel Management Corporation is in the business of, *inter alia*, developing, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products throughout the United States, including within this District, either on its own or through

its affiliates, including Avadel US Holdings, Inc., Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, and Avadel CNS Pharmaceuticals LLC.

ANSWER: Defendants admit that Avadel Management Corporation is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri 63005. Except as otherwise admitted, the allegations are denied as stated.

10. On information and belief, Defendant Avadel CNS Pharmaceuticals LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri 63005. On information and belief, Avadel CNS Pharmaceuticals LLC is in the business of, *inter alia*, developing, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products throughout the United States, including within this District, either on its own or through its affiliates, including Avadel US Holdings, Inc., Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, and Avadel Management Corporation.

ANSWER: Defendants admit that Avadel CNS Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware and has its principal place of business at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri 63005. Defendants admit that Avadel CNS Pharmaceuticals, LLC develops, manufactures, and imports pharmaceutical products throughout the United States. Defendants deny the remaining allegations in Paragraph 10.

11. On information and belief, Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, Avadel Management Corporation, and Avadel CNS Pharmaceuticals LLC are wholly-owned subsidiaries of Avadel US Holdings, Inc.

ANSWER: Admitted.

12. On information and belief, following any FDA approval of their NDA for a sodium oxybate product, Defendants Avadel Pharmaceuticals plc, Avadel US Holdings, Inc., Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, Avadel Management Corporation, and Avadel CNS Pharmaceuticals LLC will work in concert with one another to make, use, offer to sell, and/or sell the product that is the subject of their NDA for a sodium oxybate product throughout the United States, and/or import such a product into the United States.

ANSWER: Defendants admit that Avadel filed an NDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. Defendants deny the remaining allegations in Paragraph 12.

Jurisdiction and Venue

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: The allegations in Paragraph 13 state legal conclusions to which no response is required. To the extent a response is required, Defendants do not dispute subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Except as otherwise admitted, the allegations are denied as stated.

14. On information and belief, Avadel Pharmaceuticals plc is subject to personal jurisdiction in Delaware because Avadel Pharmaceuticals plc has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in Delaware. On information and belief, Avadel Pharmaceuticals plc manufactures, markets, offers for sale, and/or sells drug products throughout the United States and within the State of Delaware and, therefore, transacts business within the State of Delaware related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

ANSWER: The allegations in Paragraph 14 state legal conclusions to which no response is required. To the extent a response is required, Defendants do not dispute whether Avadel Pharmaceuticals plc is subject to personal jurisdiction in Delaware for purposes of this action only. Except as otherwise admitted, the allegations are denied as stated.

15. On information and belief, Avadel US Holdings, Inc. is subject to personal jurisdiction in Delaware because Avadel US Holdings, Inc. has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in Delaware. Avadel US Holdings, Inc. is a corporation organized and existing under the laws of the State of Delaware. On information and belief, Avadel US Holdings, Inc. manufactures, markets, imports, offers for sale, and/or sells drug products throughout the United States and within the State of Delaware and, therefore, transacts business within the State of

Delaware related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. On information and belief, Avadel US Holdings, Inc. is registered to do business in Delaware (business identification number 5123065) and has appointed Corporate Creations Network Inc., located at 3411 Silverside Road Tatnall, Building, Suite 104, Wilmington, Delaware 19810, as its registered agent for the receipt of service of process.

ANSWER: Defendants admit that Avadel US Holdings, Inc. is a corporation organized and existing under the laws of the State of Delaware. Defendants do not dispute whether Avadel US Holdings, Inc. is subject to personal jurisdiction in Delaware for purposes of this action only. Except as otherwise admitted, the allegations are denied as stated.

16. On information and belief, Avadel Specialty Pharmaceuticals, LLC is subject to personal jurisdiction in Delaware because Avadel Specialty Pharmaceuticals, LLC has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in Delaware. Avadel Specialty Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware. On information and belief, Avadel Specialty Pharmaceuticals, LLC manufactures, markets, imports, offers for sale, and/or sells drug products throughout the United States and within the State of Delaware and, therefore, transacts business within the State of Delaware related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. On information and belief, Avadel Specialty Pharmaceuticals, LLC is registered to do business in Delaware (business identification number 6507288) and has appointed Corporate Creations Network Inc., located at 3411 Silverside Road Tatnall, Building, Suite 104, Wilmington, Delaware 19810, as its registered agent for the receipt of service of process.

ANSWER: Defendants admit that Avadel Specialty Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware. Defendants do not dispute whether Avadel Specialty Pharmaceuticals, LLC is subject to personal jurisdiction in Delaware for purposes of this action only. Except as otherwise admitted, the allegations are denied as stated.

17. On information and belief, Avadel Legacy Pharmaceuticals, LLC is subject to personal jurisdiction in Delaware because Avadel Legacy Pharmaceuticals, LLC has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in Delaware. Avadel Legacy Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware. On information and belief, Avadel Legacy Pharmaceuticals, LLC manufactures, markets, imports, offers for sale, and/or sells drug products throughout the United States and within the State of Delaware and, therefore, transacts business within the State of Delaware related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. On

information and belief, Avadel Legacy Pharmaceuticals, LLC is registered to do business in Delaware (business identification number 4886228) and has appointed Corporate Creations Network Inc., located at 3411 Silverside Road Tatnall, Building, Suite 104, Wilmington, Delaware 19810, as its registered agent for the receipt of service of process.

ANSWER: Defendants admit that Avadel Legacy Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of the State of Delaware. Defendants do not dispute whether Avadel Legacy Pharmaceuticals, LLC is subject to personal jurisdiction in Delaware for purposes of this action only. Except as otherwise admitted, the allegations are denied as stated.

18. On information and belief, Avadel Management Corporation is subject to personal jurisdiction in Delaware because Avadel Management Corporation has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in Delaware. Avadel Management Corporation is a corporation organized and existing under the laws of the State of Delaware. On information and belief, Avadel Management Corporation manufactures, markets, imports, offers for sale, and/or sells drug products throughout the United States and within the State of Delaware and, therefore, transacts business within the State of Delaware related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. On information and belief, Avadel Management Corporation is registered to do business in Delaware (business identification number 6201113) and has appointed Corporate Creations Network Inc., located at 3411 Silverside Road Tatnall, Building, Suite 104, Wilmington, Delaware 19810, as its registered agent for the receipt of service of process.

ANSWER: Defendants admit that Avadel Management Corporation is a corporation organized and existing under the laws of the State of Delaware. Defendants do not dispute whether Avadel Management Corporation is subject to personal jurisdiction in Delaware for purposes of this action only. Except as otherwise admitted, the allegations are denied as stated.

19. On information and belief, Avadel CNS Pharmaceuticals LLC is subject to personal jurisdiction in Delaware because Avadel CNS Pharmaceuticals LLC has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in Delaware. Avadel CNS Pharmaceuticals LLC is a limited liability company organized and existing under the laws of the State of Delaware. On information and belief, Avadel CNS Pharmaceuticals LLC manufactures and imports drug products throughout the United States and within the State of Delaware and, therefore, transacts business within the State of Delaware related to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware. On information and belief, Avadel CNS Pharmaceuticals LLC is registered to do business in Delaware (business identification number 7734658) and has appointed

Corporate Creations Network Inc., located at 3411 Silverside Road Tatnall, Building, Suite 104, Wilmington, Delaware 19810, as its registered agent for the receipt of service of process.

ANSWER: Admitted.

20. On information and belief, Avadel Pharmaceuticals plc, Avadel US Holdings, Inc., Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, Avadel Management Corporation, and Avadel CNS Pharmaceuticals LLC are agents and/or alter egos of one another and work in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of pharmaceutical products throughout the United States, including in this Judicial District.

ANSWER: The allegations in Paragraph 20 state legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 20.

21. On information and belief, by virtue of, *inter alia*, Defendants' continuous and systematic contacts with Delaware, including, but not limited to, the above-described contacts, and the actions on behalf of Defendants in connection with their NDA seeking FDA approval to commercially market a sodium oxybate drug product, this Court has personal jurisdiction over Defendants. These activities satisfy due process and confer personal jurisdiction over Defendants consistent with Delaware law.

ANSWER: The allegations in Paragraph 21 state legal conclusions to which no response is required. To the extent a response is required, Defendants do not dispute whether they are subject to personal jurisdiction in Delaware for purposes of this action only. Defendants deny the remaining allegations in Paragraph 21.

22. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: The allegations in Paragraph 22 state legal conclusions to which no response is required. To the extent a response is required, Defendants do not challenge venue for purposes of this action only. Defendants deny the remaining allegations in Paragraph 22.

The Patent-In-Suit

23. On August, 3 2021, the USPTO duly and lawfully issued the '079 patent entitled, "GHB formulation and method for its manufacture." A copy of the "'079 patent" is attached hereto as Exhibit A.

ANSWER: Defendants admit that the USPTO issued the '079 patent on August 3, 2021, and that the patent is entitled "GHB formulation and method for its manufacture." Defendants admit that Exhibit A appears to be a copy of the '079 patent. Defendants deny that the '079 patent was duly and lawfully issued. Defendants deny the remaining allegations in Paragraph 23.

Background

24. Jazz Pharmaceuticals holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for sodium oxybate oral solution (NDA No. 21-196), which it sells under the trade name XYREM®. The claims of the '079 patent cover, *inter alia*, methods of use and administration of pharmaceutical compositions containing sodium oxybate. Jazz Pharmaceuticals owns the patent-in-suit.

ANSWER: On information and belief, Defendants state that Jazz is the purported holder of NDA No. 21-196 for sodium oxybate oral solution. On information and belief, the product that is the subject of NDA No. 21-196 is marketed under the trade name Xyrem. The remaining allegations in Paragraph 24 state legal conclusions to which no response is required. To the extent a response is required, Defendants refer to the patent-in-suit for its content and deny any allegations inconsistent with those contents. Defendants lack sufficient information to form a belief as to whether Jazz owns the patent-in-suit, but note that Jazz Pharmaceuticals Ireland Limited is listed on the face of the patent-in-suit. Defendants deny the remaining allegations in Paragraph 24.

Acts Giving Rise to This Suit

25. Pursuant to Section 505(b)(2) of the FFDCA, Avadel filed an NDA ("Avadel's NDA") seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of a sodium oxybate product ("Avadel's Proposed Product"), before the patent-in-suit expires.

ANSWER: Defendants admit that Avadel filed an NDA pursuant to Section 505(b)(2) of the FFDCA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. Defendants

admit that the patent-in-suit has not yet expired. Defendants deny the remaining allegations in Paragraph 25.

26. On December 16, 2020, Avadel announced the submission of its NDA to the FDA. On information and belief, on February 26, 2021, the FDA notified Avadel of formal acceptance of Avadel's NDA with an assigned Prescription Drug User Fee Act ("PDUFA") target action date of October 15, 2021.[1]

ANSWER: Defendants admit that on December 16, 2020, Defendant Avadel Pharmaceuticals plc announced Avadel's submission of its NDA to the FDA, and on February 26, 2021, the FDA notified Avadel of formal acceptance of its NDA with an assigned PDUFA target action date of October 15, 2021. Defendants deny the remaining allegations in Paragraph 26.

27. Avadel has identified its Proposed Product using the code name FT218.[2]

ANSWER: Admitted.

28. Avadel has published data comparing the pharmacokinetic properties of Avadel's Proposed Product with twice-nightly sodium oxybate (i.e., XYREM®).[3]

ANSWER: Defendants admit that the article cited in footnote 3 of the Complaint was published, and that Exhibit C appears to be an accurate copy of the article. Defendants refer to the article cited in footnote 3 for its content and deny any allegations inconsistent with that content. Defendants deny the remaining allegations in Paragraph 28.

29. Avadel owns U.S. Patent No. 10,272,062 ("Avadel's '062 patent") entitled "Modified Release Gamma-Hydroxybutyrate Formulations Having Improved Pharmacokinetics," attached hereto as Exhibit B.

ANSWER: Denied.

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[1] *See* Avadel's 2020 Annual Report at p. 7 (available at https://www.sec.gov/ix?doc=/Archives/edgar/data/1012477/000101247721000004/avdl-20201231.htm)

[2] *See id.*

[3] *Seiden, et al.*, Pharmacokinetics of FT218, a Once-Nightly Sodium Oxybate Formulation in Healthy Adults, Clin. Ther. 2021 Feb 22; S0149-2918(21)00044-8; doi:10.1016/j.clinthera.2021.01.017, attached hereto as Exhibit C

30. On information and belief, Avadel's published data concerning the pharmacokinetic properties of Avadel's Proposed Product correspond to the Examples of Avadel's '062 patent.

ANSWER: Defendants refer to any published data concerning the pharmacokinetic properties of Avadel's Proposed Product for their contents and deny any allegations inconsistent with those contents. Defendants deny the remaining allegations in Paragraph 30.

31. On information and belief, Avadel's Proposed Product is an embodiment of the claims of Avadel's '062 patent.

ANSWER: The allegations in Paragraph 31 state legal conclusions to which no response is required. To the extent a response is required, Defendants refer to the '062 patent for its content and deny any allegations inconsistent with those contents. Defendants deny the remaining allegations in Paragraph 31.

32. On information and belief, the formulations of gamma-hydroxybutyrate described in Avadel's '062 patent are preferably supplied in sachets.[4]

ANSWER: Defendants refer to the portion of the '062 patent cited in footnote 4 for its content and deny any allegations inconsistent with those contents. Defendants deny the remaining allegations in Paragraph 32.

33. On information and belief, Avadel's Proposed Product, FT218, will be made available in unit dose-sachets at 4.5 gram, 6 gram, 7.5 gram, and 9 gram doses.[5]

ANSWER: Defendants refer to the transcript cited in footnote 5 for its content and deny any allegations inconsistent with those contents. Defendants deny the remaining allegations in Paragraph 33.

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[4] *See* Avadel's '062 patent at 44:7-17 ("The modified release formulation of gamma-hydroxybutyrate is preferably supplied in sachets or stick-packs comprising a particulate formulation.")

[5] *See* Avadel's March 8, 2018 Q1 2018 Earnings Call Transcript, attached hereto as Exhibit D.

34. On information and belief, the sachets containing the formulations described in Avadel's '062 patent are meant to be opened and their contents mixed with water to provide the nightly dose of gamma-hydroxybutyrate.[6]

ANSWER: Defendants refer to the document cited in footnote 6 for its content and deny any allegations inconsistent with those contents. Defendants deny the remaining allegations in Paragraph 34.

35. On information and belief, Avadel's Proposed Product, FT218, is covered by Jazz Pharmaceuticals' '079 patent.

ANSWER: Denied.

36. On information and belief, Avadel has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell, and/or import Avadel's Proposed Product prior to expiration of the patent-in-suit.[7] Avadel recently confirmed that it has "accelerated" its launch planning for its Proposed Product.[8]

ANSWER: Defendants admit that Avadel filed an NDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. Defendants admit that the patent-in-suit has not yet expired. Defendants refer to the documents cited in footnotes 7 and 8 for their contents and deny any allegations inconsistent with their contents. Defendants deny the remaining allegations in Paragraph 36.

37. On information and belief, Avadel continues to seek approval of its NDA from the FDA and, if approved, intends to commercially have Avadel's Proposed Product manufactured for marketing and sale in the United States.

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[6] *See* Avadel's '062 patent at 31:55-65; *id.* at 44:7-17; see also Exhibit C at 3.

[7] *See* Avadel's 2020 Annual Report at pp. 18, 29, 48 (available at https://www.sec.gov/ix?doc=/Archives/edgar/data/1012477/000101247721000004/avdl-20201231.htm); see also Avadel's March 9, 2021 Q4 2020 Earnings Call Transcript, attached hereto as Exhibit E.

[8] *See* Avadel's May 10, 2021 Q1 2021 Earnings Call Transcript, attached hereto as Exhibit F.

ANSWER: Defendants admit that Avadel filed an NDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. Defendants deny the remaining allegations in Paragraph 37.

Count for Infringement of the '079 Patent

38. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Defendants incorporate their response to the allegations in Paragraphs 1-37 as if fully set forth in this paragraph.

39. Avadel, by the submission of its NDA to the FDA, has indicated that it seeks approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Avadel's Proposed Product, prior to the expiration of the '079 patent.

ANSWER: Defendants admit that Avadel filed an NDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. Defendants admit that the claims of the '079 patent have not yet expired. Defendants deny the remaining allegations in Paragraph 39.

40. Avadel's NDA has been pending before the FDA since at least December 16, 2020, the date that Avadel announced the submission of its NDA to the FDA.

ANSWER: Defendants admit that Avadel filed an NDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy on or about December 16, 2020, and that its NDA is currently pending. Defendants deny the remaining allegations in Paragraph 40.

41. Avadel's submission of its NDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Avadel's Proposed Product, prior to the expiration of the '079 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

ANSWER: Defendants admit that Jazz brought a claim of infringement of the '079 patent under 35 U.S.C. § 271(e)(2)(A). Defendants deny any and all remaining allegations and/or legal conclusions set forth in Paragraph 41.

42. There is a justiciable controversy between the parties hereto as to the infringement of the '079 patent.

ANSWER: Defendants admit that there is an actual case or controversy between Jazz and Avadel but deny that Jazz's allegations are valid or sustainable. Defendants deny the remaining allegations in Paragraph 42.

43. Avadel has made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Avadel's Proposed Product prior to the expiration of the '079 patent.

ANSWER: Defendants admit that Avadel filed an NDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. Defendants admit that the claims of the '079 patent have not yet expired. Defendants deny the remaining allegations in Paragraph 43.

44. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will infringe one or more claims of the '079 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Avadel's Proposed Product in the United States.

ANSWER: Denied.

45. Unless enjoined by this Court, upon FDA approval of Avadel's NDA, Avadel will induce infringement of one or more claims of the '079 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Avadel's Proposed Product in the United States. On information and belief, upon FDA approval of Avadel's NDA, Avadel will encourage acts of direct infringement with knowledge of the '079 patent and

knowledge that its acts are encouraging infringement, with specific intent to induce infringement of the ’079 patent.

ANSWER: Denied.

46. Unless enjoined by this Court, upon FDA approval of Avadel’s NDA, Avadel will contributorily infringe one or more claims of the ’079 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Avadel’s Proposed Product in the United States. On information and belief, Avadel has had and continues to have knowledge that Avadel’s Proposed Product is especially adapted for a use that infringes one or more claims of the ’079 patent and that there is no substantial non-infringing use for Avadel’s Proposed Product.

ANSWER: Denied.

47. Plaintiffs will be substantially and irreparably damaged and harmed if Avadel’s infringement of the ’079 patent is not enjoined.

ANSWER: Denied.

48. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Avadel’s Proposed Product prior to expiration of the ’079 patent by Avadel will constitute direct infringement, induced infringement, and/or contributory infringement of the ’079 patent.

ANSWER: Denied.

49. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

50. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys’ fees under 35 U.S.C. § 285.

ANSWER: Denied.

Jazz’s Prayer for Relief

WHEREFORE, Plaintiff respectfully requests the following relief:

(A) A Judgment be entered that Avadel has infringed the patent-in-suit by submitting its NDA for its sodium oxybate drug product;

(B) A Judgment be entered that Avadel has infringed, and that Avadel’s making, using, selling, offering to sell, and/or importing Avadel’s Proposed Product will infringe one or more claims of the patent-in-suit;

(C) An Order that the effective date of FDA approval of Avadel's NDA for its sodium oxybate drug product be a date which is not earlier than the later of the expiration of the patent-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(D) Preliminary and permanent injunctions enjoining Avadel and its officers, agents, attorneys and employees, and those acting in privity and/or concert with them, from making, using, selling, offering to sell, and/or importing Avadel's Proposed Product until after the expiration of the patent-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(E) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Avadel, its officers, agents, attorneys and employees, and those acting in privity and/or concert with them, from practicing any methods as claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patent-in-suit, until after the expiration of the patent-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(F) A Declaration that the commercial manufacture, use, sale, or offer for sale, and/or importation into the United States of Avadel's Proposed Product will directly infringe, induce, and/or contribute to infringement of the patent-in-suit;

(G) To the extent that Avadel has committed any acts with respect to the methods claimed in the patent-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), that Plaintiffs be awarded damages for such acts;

(H) If Avadel engages in the commercial manufacture, use, sale, or offer for sale, or importation into the United States of Avadel's Proposed Product prior to the expiration of the patent-in-suit, a Judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

(I) Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

(J) Costs and expenses in this action; and

(K) Such further and other relief as this Court may deem just and proper.

ANSWER: Paragraphs (A)-(K) set forth Jazz's prayer for relief to which no response is required. To the extent that responses to these paragraphs are required, Defendants deny any allegations set forth therein and deny that Jazz is entitled to any relief, including a permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) as, *inter alia*, Jazz is not entitled to relief under said provision.

DEFENSES

Subject to the responses above, upon information and belief, Defendants allege and assert at least the following defenses in response to Jazz's allegations, undertaking the burden of proof

only as to those defenses deemed affirmative defenses by law, regardless of how such defenses are named herein. In addition to the defenses described below, subject to the responses above, Defendants specifically reserve all rights to allege additional defenses that are not required to be pleaded or that become known through the course of discovery.

FIRST DEFENSE
(Non-Infringement)

1. Defendants have not infringed, do not directly or indirectly infringe (either by induced infringement or contributory infringement), and upon approval of the NDA for FT218, will not infringe any valid, enforceable, asserted claim of the '079 patent, either literally or under the doctrine of equivalents, or under any theory of infringement.

SECOND DEFENSE
(Invalidity)

2. Each of the asserted claims of the '079 patent is invalid for failure to comply with one or more conditions of patentability set forth in 35 U.S.C. §§ 101, 102, 103, 112, 115, and/or 116.

THIRD DEFENSE
(Prosecution History Disclaimer and Estoppel)

3. Jazz is barred, based on statements, representations, and admissions made during prosecution of the patent applications resulting in the asserted patent or related patent applications, from asserting any interpretation of any valid, enforceable claim of the asserted patent that would be broad enough to cover any accused product or method alleged to infringe the asserted patent, either literally or by application of the doctrine of equivalents, or under any theory of infringement.

FOURTH DEFENSE
(Failure to State A Claim Upon Which Relief Can Be Granted)

4. Jazz's Complaint fails to state a claim upon which relief can be granted.

FIFTH DEFENSE
(Patent Misuse)

5. By its conduct, Jazz has engaged in patent misuse by asserting infringement claims it knows or should have known are meritless.

SIXTH DEFENSE
(Inequitable Conduct)

6. Jazz's attempted enforcement of the asserted patent against Defendants is barred by inequitable conduct for the reasons described in paragraphs 10 to 59 of Avadel's below counterclaim.

SEVENTH DEFENSE
(Unclean Hands)

7. Jazz's attempted enforcement of the asserted patent against Defendants is barred by the equitable doctrine of unclean hands for the reasons described in paragraphs 10 to 62 of Avadel's below counterclaim.

EIGHTH DEFENSE
(No Willfulness)

8. Jazz is barred from seeking and/or obtaining a finding of willfulness or receiving enhanced damages because Jazz has failed to allege Defendants engaged in any willful infringement or reprehensible conduct and Defendants have engaged in no such conduct, which is a prerequisite for a finding of willfulness and an award of enhanced damages.

NINTH DEFENSE
(Attorneys' Fees)

9. Jazz has failed to state facts sufficient to support an award of attorneys' fees.

TENTH DEFENSE
(Limitations on Costs)

10. To the extent that Jazz prevails on any of its allegations, its demand for costs is limited or barred pursuant to 35 U.S.C. § 288 because claims of the asserted patent are invalid.

ELEVENTH DEFENSE
(Improper Hatch-Waxman Suit)

11. Jazz's infringement claims brought pursuant to the Hatch-Waxman Statute are improper, including because Jazz is not entitled to any relief under that Statute, including a permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B).

TWELFTH DEFENSE
(Other Defenses)

12. Defendants reserve the right to supplement or amend this Answer and reserve all defenses set out in Rule 8(c) of the Federal Rules of Civil Procedure, the Patent Laws of the United States, and any other defenses, at law or in equity, which become applicable during the course of discovery or otherwise in the course of litigation.

AVADEL'S COUNTERCLAIMS

1. Defendants' Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

2. The Court has subject matter jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338.

3. Venue in this District is proper pursuant to 28 U.S.C. §§ 1391(b), (c), and 1400(b).

4. Counterclaim-Plaintiff Avadel CNS Pharmaceuticals, LLC ("Avadel") is a limited liability company organized and existing under the laws of the State of Delaware and has its principal place of business at 16640 Chesterfield Grove Road, Suite 200, Chesterfield, Missouri 63005.

5. Upon information and belief, Counterclaim-Defendant Jazz Pharmaceuticals, Inc. ("Jazz") is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 3170 Porter Drive, Palo Alto, California 94304.

Preliminary Statement

6. Flamel Ireland Limited, a wholly-owned subsidiary of Avadel Pharmaceuitcals plc, owns numerous United States patents that cover Avadel's innovative product FT218, a once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. One of those patents, U.S. Pat. No. 10,952,986 (the "'986 patent"), entitled "Modified Release Gamma-Hydroxybutyrate Formulations Having Involved Pharmacokinetics," was filed on May 23, 2019 as application number 16/420,321 (the "'321 application"), and issued on March 23, 2021. The '321 application claims priority to several provisional applications with the earliest provisional application No. 62,365,812 filed on July 22, 2016.

7. At the time the '321 application was published on September 12, 2019, Jazz had not filed the patent application that ultimately issued as Jazz's asserted '079 patent.

8. Jazz did not file the application that ultimately led to the issuance of the '079 patent until December 10, 2020 – more than a year ***after*** the '321 application was published.

9. On information and belief, Jazz drafted the claims that ultimately issued as the '079 patent based not on any commensurate disclosure of its underlying application, but solely in view of the disclosures set forth in the '321 application. The '079 patent specification only discloses embodiments of a formulation for purported once-daily dosing that utilize one or more ion exchange resins. And yet, Jazz has asserted that one or more claims of the '079 patent would be infringed through the use of Avadel's FT218, which does not include any such ion exchange resin. Given Jazz's view of the claim scope of the '079 patent, the '079 patent claims as filed and issued are neither described nor supported by its specification as, on information and belief, the claims were instead solely based on Flamel Ireland Limited's inventive work disclosed in at least the '321 application.

Count I: Declaratory Judgment of Non-Infringement of the '079 Patent

10. Avadel incorporates by reference the allegations made in Avadel's Defenses and in the preceding paragraphs of the Counterclaims above.

11. An actual controversy exists between Avadel and Jazz over the alleged infringement of at least one claim of the '079 patent. Jazz holds itself out as the owner of the '079 patent. Jazz has filed suit against Avadel alleging that the submission of Avadel's NDA infringes at least claim 1 of the '079 patent in violation of 35 U.S.C. § 271(e). Jazz has also alleged that the making, using, offering to sell, selling, and/or importation of Avadel's Proposed Product in the United States infringes at least claim 1 of the '079 patent in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

12. The submission of Avadel's NDA does not infringe the '079 patent in violation of 35 U.S.C. § 271(e), either literally or under the doctrine of equivalents. The making, using, offering to sell, selling, and/or importation of Avadel's Proposed Product in the United States would not infringe any valid claim of the '079 patent in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c), either literally or under the doctrine of equivalents. Avadel hereby seeks a declaration that the submission of Avadel's NDA, and the making, using, offering to sell, selling, and/or importation of Avadel's Proposed Product in the United States does not infringe and/or will not infringe any valid claim of the '079 patent.

13. Avadel has not infringed, is not infringing, and will not infringe any valid claim of the '079 patent, directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner. A judicial declaration is necessary and appropriate so that Avadel may ascertain its rights regarding the '079 patent.

Count II: Declaratory Judgment of Invalidity of the '079 Patent

14. Avadel incorporates by reference the allegations made in Avadel's Defenses and in the preceding paragraphs of the Counterclaims above.

15. An actual controversy exists between Avadel and Jazz over the invalidity of the '079 patent. Jazz has filed suit against Avadel alleging that the submission of Avadel's NDA infringes at least claim 1 of the '079 patent in violation of 35 U.S.C. § 271(e). Jazz has also alleged that the making, using, offering to sell, selling, and/or importation of Avadel's Proposed Product in the United States infringes at least claim 1 of the '079 patent in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c).

16. All claims of the '079 patent are invalid because they fail to comply with one or more requirements of the United States Code Title 35, including, without limitation, one or more requirements of 35 U.S.C. §§ 102, 103, 112, 115, and/or 116. Avadel expressly reserves all rights to identify and assert additional invalidity positions in this case.

17. Avadel hereby seeks a declaration that the claims of the '079 patent are invalid.

Count III: Inequitable Conduct

18. Avadel incorporates by reference the allegations made in Avadel's Defenses and in the preceding paragraphs of the Counterclaims above.

Background

19. Avadel, not Jazz, invented a once-nightly formulation of sodium oxybate. Jazz is not the true inventor of the subject claims. It derived the alleged invention from Avadel, and it concealed that fact from the patent Examiner in order to obtain the '079 patent.

20. During prosecution of the '079 patent, Jazz owed a duty of candor requiring it to disclose to the Examiner all information material to patentability. This duty included, but was not limited to, a specific duty to tell the Examiner if Jazz copied claims from another patent or

application. Jazz copied various claims in the '079 patent from one of Avadel's prior patent applications. But Jazz did not disclose its copying to the Examiner, and indeed did not even tell the Examiner about the existence of Avadel's application at all until a supplemental disclosure just months before the '079 patent issued, despite disclosing more than 200 other, less relevant prior art references. Jazz concealed its copying, and buried the reference to Avadel's application, with the specific intents of both hiding the fact that the named Jazz inventors did not invent the subject matter claimed in the '079 patent, and misleading the United States Patent and Trademark Office ("PTO") into issuing the '079 patent.

21. Had the Examiner known the truth, the PTO would not have issued the '079 patent to Jazz for various reasons, including lack of written description and for lack of novelty under § 102 in light of Avadel's earlier-filed application. And because it is impossible to conceive of a reason to hide Jazz's copying from the Examiner other than as part of an effort to mislead the Examiner, the natural and most reasonable inference is that Jazz did so with an intent to deceive the PTO. Jazz's concealment breached its duty of candor to the PTO and renders the '079 patent unenforceable.

22. Avadel has been awarded multiple patents in connection with its revolutionary new once-nightly formulation of sodium oxybate.

23. As discussed above, on May 23, 2019, Flamel Ireland Limited filed the '321 application, which eventually issued as the '986 patent on March 23, 2021.

24. Flamel Ireland Limited is today known as Avadel Ireland.

25. Unlike the specification of Jazz's '079 patent, the specification of Avadel's '321 application contains detailed information regarding modified release formulations of oxybate and methods of using those formulations therapeutically. For example, whereas Jazz's '079 patent has

no figures whatsoever, no dissolution testing, and no examples in which humans or any other animal were treated, the specification of Avadel's '321 application contains 90 figures, detailed dissolution testing, and detailed data from in vivo studies.

26. As of the May 23, 2019 filing date of the Avadel '321 application, Jazz had not filed the application leading to the '079 patent—application number 17/118,041 (the "'041 application"). Nor had it filed the parent application to the '041 application; application number 16,448,598 was filed on June 21, 2019. It had filed a *grandparent* application, application number 15/047,586 (the "'586 application"), on February 18, 2016, which would eventually issue as U.S. Patent No. 10,398,662 (the "'662 patent"). That grandparent application in turn derived from a provisional application, 62/117,889 (the "'889 provisional application"), which was filed on February 18, 2015.

27. The claims of the Avadel '321 application first became publicly available when the '321 application was published by the PTO on September 12, 2019. Some of the claims were slightly modified during prosecution, and the final version of the claims that are found in the '986 patent became publicly available when an Avadel Amendment and Response to Non Final Office Action filed October 1, 2020 was published.

28. Approximately two months later, on December 10, 2020, Jazz filed the '041 application, which eventually issued as the '079 patent. Along with Jazz's filing of the '041 application, Jazz filed a Nonpublication Request. Both the '041 application and the Nonpublication Request were signed by Jazz's outside counsel, Jason C. Valentine ("Mr. Valentine").

29. By its Nonpublication Request, Jazz sought to ensure that the '041 application would not be made public, as would ordinarily take place after the expiration of a certain period

of time following the filing of the application. As of the December 10, 2020 filing date of the '041 application and the Nonpublication Request, the specification of the '041 application had already been made public at least through the issuance of the '662 patent, as the '662 patent issued on September 3, 2019. Two new paragraphs were added to the specification of the '041 application, but Jazz represented to the Examiner that the paragraphs being inserted were "material previously incorporated by reference" and so were also previously publicly available. Accordingly, taking Jazz's argument at face value, the only reasonable inference that can be drawn from the filing of the Nonpublication Request with respect to the '041 application is that Jazz was seeking to prevent others from learning what claims Jazz was pursuing in the '041 application. Those claims were literally the only thing in the "nonpublished" patent application that were not already published. On information and belief, Jazz sought to prevent Avadel in particular from learning that the claims that Jazz was pursuing were largely copied from Avadel's '321 application.

30. The table below shows the first seven claims of Avadel's '321 application on the left and the first seven claims of Jazz's later filed '041 application on the right.

Claims from Avadel's Patent Application No. 16/420,321, Amendment and Response to Non Final Office Action, filed October 1, 2020	**Claims from Jazz's Patent Application No. 17/118,041, filed December 10, 2020**
1. A method of treating a disorder treatable with gamma-hydroxybutyrate in a human in need thereof, the method comprising: administering a single daily dose to said human, the single daily dose comprising an amount of gamma-hydroxybutyrate equivalent to from 3.0 to 12.0 g of sodium oxybate, wherein the administering comprises opening a sachet containing a gamma-hydroxybutyrate formulation, mixing the formulation with water, and orally administering the mixture.	1. A method of treating a disease or condition treatable with oxybate in a patient in need thereof, the method comprising: administering a single daily dose to the patient, the single daily dose comprising an amount of oxybate equivalent to from 4.0 g to 12.0 g of sodium oxybate, wherein the administering comprises: opening a sachet containing an oxybate formulation, mixing the formulation with water, and orally administering the mixture to the patient.
2. The method of claim 1, wherein the orally administering occurs at bedtime.	2. The method of claim 1, wherein the orally administering occurs at night.
3. The method of claim 1, wherein the mixing occurs shortly before the orally administering.	3. The method of claim 1, wherein the oxybate formulation is mixed with water immediately prior to administration.
4. The method of claim 1, wherein the orally administering occurs approximately 2 hours after said human has eaten a meal.	4. The method of claim 1, wherein the oxybate is administered with food.
5. The method of claim 1, wherein said administering results in inducing said human to sleep for 6 to 8 hours.	5. The method of claim 1, wherein the administering promotes the patient to sleep for 6 to 8 hours.
6. The method of claim 1, wherein the amount of gamma-hydroxybutyrate administered to the human is equivalent to 4.5 g, 6.0 g, 7.5 g or 9.0 g of sodium oxybate.	6. The method of claim 1, wherein the amount of oxybate administered to the human is 35 mEq, 45 mEq, 60 mEq, or 70 mEq of oxybate.
7. The method of claim 1, wherein the mixture is a suspension.	7. The method of claim 1, wherein the mixture is a suspension.

31. As is clear from a side-by-side comparison, claims of Jazz's '041 application that issued as the '079 patent are strikingly similar to publicly available claims of Avadel's '321

application. The similarity is far too close to be accidental. The only reasonable explanation is that Jazz copied Avadel's claims.

32. The breadth and depth of such copying cannot be the result of happenstance. On information and belief, Jazz, through its agent Mr. Valentine, intentionally copied the Avadel claims.

33. Jazz and Mr. Valentine never disclosed to the Examiner that they had copied claims in Jazz's '041 application from Avadel's '321 application.

34. On December 21, 2020, Jazz filed an Information Disclosure Statement ("IDS") signed by Mr. Valentine that listed 204 references but did not include Avadel's '321 application.

35. On February 24, 2021, the Examiner issued a Non-Final Rejection, rejecting all claims of the '041 application as being invalid under 35 U.S.C. § 103.

36. On March 3, 2021, Avadel's '986 patent issued.

37. On April 26, 2021, an applicant-initiated interview with the Examiner took place via video conference. Mr. Valentine participated in the interview for Jazz, as did Phil McGarrigle (another attorney of record for Jazz) and named inventor Clark Allphin. At the interview, Jazz, through Mr. Valentine, Mr. McGarrigle, and Mr. Allphin, argued that sachet dosages like those recited in the claims were not obvious.

38. A slide deck made of record in the file history of the '041 application demonstrates that Mr. Valentine and/or Mr. McGarrigle told the Examiner that the '041 application was a part of Jazz's patent portfolio that "goes back to 1999." They represented to the Examiner that a sachet containing a solid, once-nightly unit dose product represented an advance for patients with respect to convenience, compliance, and safety. They then argued that the prior art cited by the Examiner did not provide a motivation to prepare such a sachet formulation. On information and belief,

none of Mr. Valentine, Mr. McGarrigle, or Mr. Allphin informed the Examiner during this interview of (1) the existence of the '321 application; (2) that Jazz had copied the claims of the '041 application from Avadel's '321 application; (3) that they had not in fact invented a once-nightly formulation of oxybate in 1999 or at any time thereafter, and (4) that it was Avadel and not Jazz that had developed a sachet formulation of oxybate.

39. On April 27, 2021, Jazz filed an Information Disclosure Statement ("IDS") signed by Mr. Valentine that listed 33 references, including Avadel's '321 application and Avadel's resulting '986 patent. Jazz and Mr. Valentine did not disclose to the Examiner that Avadel's '321 application was the source of claims in Jazz's '041 application. Jazz and Mr. Valentine's suppression of evidence is an affirmative act of egregious misconduct. Nor did they offer any explanation for why they had not disclosed Avadel's '321 application in their initial IDS.

40. On May 20, 2021, Mr. Valentine filed and signed an Amendment and Request for Reconsideration after Non-Final Rejection to overcome prior art relied on by the Examiner to reject the claims in Jazz's '041 application as obvious. Included with this filing in support of Jazz's attempt to overcome the obviousness rejections was a signed declaration of named inventor Clark Allphin that addressed technical issues and the prior art cited by the Examiner. In his declaration, Mr. Allphin represented that the '041 application was entitled to a 2015 filing date, *i.e.*, the date of the '889 provisional application. *See* Allphin Declaration at ¶ 5 ("In fact, when the present application was filed in 2015 . . ."). Mr. Allphin also declared that the references relied upon by the Examiner did not render the pending claims obvious because, among other reasons, they were not about using oxybate in sachet form for once-a-day administration. *See* Allphin Declaration at ¶¶ 7-8 ("No cited reference describes or suggests administering a solid oxybate formulation in a sachet dosage form let alone according to a once-a-day administration schedule.

. . . *Alshaikh* does not suggest using a sachet dosage form . . . . *Luhn* does not relate to oxybate at all . . . .”). Mr. Allphin also represented that “according to *Luhn*, sachets are common in the confectionary field but less so in pharmaceutical industry because of regulatory and manufacturing challenges.” *Id.* at ¶ 8. Mr. Allphin also declared that in his experience, “pharmaceutical developers prefer to rely on known, proven technologies for product development.” *Id.* Mr. Valentine repeated these arguments and directed the Examiner to the Allphin declaration in the May 20, 2021 submission that he signed.

41. Neither the Amendment and Request for Reconsideration signed by Mr. Valentine nor the declaration signed by Mr. Allphin disclosed the claim copying or that Avadel’s ’321 application (which by then had issued as the ’986 patent) was the source of the first seven claims of Jazz’s ’041 application. Instead, Mr. Valentine and Mr. Allphin continued to intentionally withhold this information from the Examiner, and thus engaging in affirmative egregious misconduct. Nor did they disclose that their sworn statement that “no cited reference describes or suggests administering a solid oxybate formulation in a sachet dosage form let alone according to a once-a-day administration schedule” was false, because Avadel’s ’321 application described exactly that. Jazz’s submission of an unmistakably false affidavit is an affirmative act of egregious misconduct.

42. Mr. Allphin and Mr. Valentine also did not inform the Examiner that, contrary to Mr. Allphin’s assertion that pharmaceutical companies would not develop a sachet form of oxybate, Avadel was developing a sachet form of oxybate, and that indeed, the pending claims were copied from an Avadel patent application on that very subject.

43. Mr. Valentine participated throughout the prosecution of the Jazz's '041 application that issued as the '079 patent, including signing amendments and remarks, IDSs, and participating as attorney of record for Jazz in Examiner interviews.

44. On information and belief, Mr. Valentine was aware of Avadel's '321 application and its claims before Jazz's '041 application was filed.

45. Mr. Valentine had a duty to disclose the source of the '041 application claims and the claim copying to the Examiner under Manual of Patent Examining Procedure 2001.06(d) [R-08.2017] and 37 CFR 11.804 and 78 FR 20179 at 20188. That duty was independent of a general duty to disclose prior art. Applicants and their counsel have a separate, independent duty to call the PTO's attention to the fact that they have copied their patent claims from another source. On information and belief, Mr. Valentine intentionally withheld this information from the Examiner and failed to comply with his duty of disclosure.

46. A patent applicant has a duty to disclose the true and correct inventors of the claimed invention. Jazz deliberately misled the PTO as to the true and correct inventors, and has therefore engaged in affirmative acts of egregious misconduct. The named inventors of the '079 patent did not invent the first seven claims of Jazz's '041 application that resulted in the '079 patent. Rather, on information and belief, Mr. Valentine copied, and in some cases slightly modified, the first seven claims from Avadel's published '321 application and used those claims as the basis for the first 7 claims of Jazz's '041 application. Mr. Valentine did not tell the patent Examiner for the '041 application that he had copied Jazz's '041 application claims from Avadel's published '321 application, and instead withheld this fact from the Examiner. Nor did the named inventors of the '041 application invent a once-nightly sachet formulation that is the basis of those claims. Rather, they copied the invention from the true inventors – Claire Megret, Herve Guillard,

and Jean-Fancois Dubuisson, who filed Avadel's '321 application. Instead, the Jazz actors, including at least Mr. Valentine, wrongly resubmitted an inaccurate inventor's oath claiming that the named inventors were the"original inventor or an original joint inventor of a claimed invention in the application" of the subject matter at issue. *See, e.g.*, MPEP 2157 ("Where an application names an incorrect inventorship, the applicant should submit a request to correct inventorship under 37 CFR 1.48").

47. Even if Jazz had not deliberately copied the invention from Avadel and intentionally withheld that fact from the patent Examiner, its deliberate decision to withhold the '321 application during the initial IDS and the main substantive patent prosecution was independently inequitable conduct. The Avadel '321 application was unquestionably the closest piece of prior art to the claimed invention. Indeed, as shown above, it was virtually identical. It was prior art, having an earlier filing date than Jazz's application and indeed an earlier filing date than Jazz's parent application. And there is no question that Mr. Valentine was aware of the application from the outset of prosecution. Jazz's deliberate decision to withhold the most relevant piece of prior art until after filing a motion for reconsideration mere weeks before the patent issued, while disclosing more than 200 less relevant references, was calculated to hide from the Examiner a prior art reference that unquestionably anticipated the claims.

Avadel is Entitled to A Declaratory Judgment of Unenforceability of the '079 Patent Due to Jazz's Inequitable Conduct

48. As is clear from the similarity of the first seven published claims in Avadel's '321 application and the first seven claims in Jazz's later filed '041 application, Mr. Valentine knew of the patent claims from Avadel's '321 application that were made publicly available in October 2020.

49. Mr. Valentine copied the first seven claims of Avadel's '321 application as the basis for the first seven claims of Jazz's '041 application that issued as the '079 patent.

50. Jazz and Mr. Valentine sought to hide this copying from the Examiner, Avadel, and the public for as long as possible.

51. Mr. Valentine attempted to hide the claim copying from the Examiner by filing the December 21, 2020 IDS with 204 references but intentionally omitting from that IDS Avadel's '321 application that was the source of claims in Jazz's '041 application, even though Mr. Valentine knew of Avadel's '321 application before filing the December 21, 2020 IDS.

52. Jazz and Mr. Valentine further sought to hide the claim copying from Avadel and the public by filing a Nonpublication Request. Jazz and Mr. Valentine knew that if the claims in Jazz's '041 application were public, Jazz's copying of Avadel's claims would be immediately apparent to Avadel, and Avadel would have been able to file a derivation proceeding challenging Jazz's effort to copy its invention. By hiding the '041 application and the copied claims from public view, Jazz and Mr. Valentine prevented Avadel from filing a derivation proceeding and kept the claim copying and issuance secret.

53. Mr. Valentine's failure to notify the PTO of the copied claims combined with Jazz's Nonpublication Request was the but-for cause of the issuance of at least claims 1-7 of the '079 patent. On information and belief, the Examiner would not have issued those claims had they been aware that the invention was copied from the earlier-filed Avadel '321 application and that Claire Megret, Herve Guillard, and Jean-Fancois Dubuisson were the true inventors.

54. Mr. Valentine did not disclose this claim copying to the PTO. Instead, Mr. Valentine intentionally withheld this claim copying and the true source of claims of Jazz's '041 application from the PTO Examiner who examined the '041 application. Upon information and

belief, Mr. Valentine withheld this information from the PTO Examiner with the intent to deceive the Examiner into thinking the named inventors of the '079 patent had come up with the original claims from Jazz's '041 application for which they were the purported inventors. That is the single most reasonable inference because there is no other reason that would explain Mr. Valentine's deliberate withholding of the most relevant piece of prior art and of the fact that he had copied that prior art directly into the '041 application. Nor is there any reason Jazz would have filed a Nonpublication Request for a patent application whose text was already published except as part of an effort to conceal the fraud and deceive the Examiner.

55. That Avadel's '321 application was the source of claims of Jazz's '041 application and that Mr. Valentine copied claims from Avadel's '321 application in writing the claims of Jazz's '041 application is but-for material information to Jazz's '041 application. Mr. Valentine knew this information, which he withheld, was but-for material to prosecution of the '079 patent.

56. Mr. Valentine had a duty to disclose the source of the '041 application claims and the claim copying to the Examiner under Manual of Patent Examining Procedure 2001.06(d) [R-08.2017] and 37 CFR 11.804 and 78 FR 20179 at 20188. Mr. Valentine intentionally withheld this information from the Examiner and failed to comply with his duty of disclosure.

57. But for Mr. Valentine withholding the source of the '041 application claims and the claim copying from the Examiner, the Examiner would have not approved claims 1-7 of the '079 patent for issuance because those claims were not invented by the named inventors of the '079 patent.

58. The '079 patent is unenforceable and void because the Jazz actors (including Mr. Valentine) violated the duty of candor and good faith in dealing with the PTO by intentionally and deceptively failing to disclose material information to the PTO during prosecution.

59. Mr. Valentine engaged in inequitable conduct during prosecution of the ’079 patent by knowingly and intentionally withholding material information about the source of Jazz’s patent claims from the PTO. But for Mr. Valentine’s knowing and intentional failure to submit this material information to the PTO, at least claims 1-7 of the ’079 patent would not have issued.

Count IV: Unclean Hands

60. Avadel incorporates by reference the allegations made in Avadel’s Defenses and in the preceding paragraphs of the Counterclaims above.

Avadel is Entitled to A Declaratory Judgment of Unenforceability of the ’079 Patent Due to Jazz’s Unclean Hands

61. As described above, the named Jazz inventors did not actually invent the subject matter of the claims identified herein, instead copying them from work by the true inventors affiliated with Avadel, falsely swore that they were the true and original inventors, and concealed their misconduct from the patent Examiner in order to obtain the ’079 patent. Doing so was misconduct by Jazz that has an immediate and necessary relation to the equity Jazz seeks with respect to this litigation. Thus, Jazz is foreclosed from asserting the ’079 patent as a result of its unclean hands.

62. Avadel seeks a dismissal of the infringement action as to the ’079 patent because the unconscionable act of one coming for relief has immediate and necessary relation to the equity that Plaintiffs seek. Jazz’s deception before the PTO relates to that relief for all the reasons stated above, namely, that Jazz misled the PTO into issuing the ’079 patent by specifically hiding the fact that the Jazz named inventors did not actually invent the subject matter claimed in the subject claims of the ’079 patent. Indeed, Jazz deceived the PTO as to the true inventor of at least claims 1-7 of the ’079 patent, concealed its copying of claims in Avadel’s ’321 application, and buried

the reference to Avadel's application. But for Jazz's deceptive conduct, at least claims 1-7 of the '079 patent would not have issued.

PRAYER FOR RELIEF

WHEREFORE, Avadel requests the following relief:

A. That the Court enter judgment against Jazz and in favor of Avadel on the claims set forth in Jazz's Complaint and that each claim be dismissed with prejudice;

B. That the Court enter judgment that Avadel does not infringe and/or will not infringe any valid claims of the asserted patent in violation of 35 U.S.C. §§ 271(a), 271(b), 271(c), and/or 271(e), or any other theory of infringement;

C. That the Court enter judgment that the asserted patent is invalid;

D. That the Court enter judgment that the asserted patent is unenforceable;

E. That the Court determine that pursuant to 35 U.S.C. § 285, Jazz's conduct in commencing and pursing this action renders this an exceptional case and award Avadel its reasonable attorneys' fees and its costs and disbursements in this action; and

F. That the Court grant Avadel such other and further relief, in law or equity, as the Court deems just and proper.

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